

# **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

## **Substance Abuse and Mental Health Services Administration Center for Mental Health Services**

**Request for Applications (RFA) No. SM 03-003**

### **Grants for**

### **State Training and Evaluation of Evidence-Based Practices**

### **Short Title: EBP Training and Evaluation**

#### **Part I - Programmatic Guidance**

**Application Due Date: March 24, 2003**

---

Gail P. Hutchings, M.P.A.  
Acting Director  
Center for Mental Health Services  
Substance Abuse and Mental Health  
Services Administration

---

Charles G. Curie, M.A., A.C.S.W.  
Administrator  
Substance Abuse and Mental Health  
Services Administration

Date of Issuance: December 2002

Catalog of Federal Domestic Assistance (CFDA) No. 93.243

Authority: Section 520A of the Public Health Service Act, as amended and subject to the availability of funds

\*This program is being announced prior to the full annual appropriation for fiscal year (FY) 2003 for the Substance Abuse and Mental Health Services Administration's (SAMHSA) programs. Applications are invited based on the assumption that sufficient funds will be appropriated for FY 2003 to permit funding of a reasonable number of applications being hereby solicited. This program is being announced in order to allow applicants sufficient time to plan and to prepare applications. Solicitation of applications in advance of a final appropriation will also enable the award of appropriated grant funds in an expeditious manner and thus allow prompt implementation and evaluation of promising projects. All applicants are reminded, however, that we cannot guarantee sufficient funds will be appropriated to permit SAMHSA to fund any applications. Questions regarding the status of the appropriation of funds should be directed to the Grants Management Officer listed under Contacts for Additional Information in this announcement.

## Table of Contents

Agency .....	3
Purpose of This Announcement .....	3
Who Can Apply? .....	3
Application Kit .....	3
How To Get an Application Kit .....	4
Where To Send the Application.....	4
Application Due Date .....	4
How To Get Help .....	4
Award Criteria .....	5
Post-Award Requirements.....	5
Program Overview .....	5
Background	
Program Goals and Objectives	
Program Structure	
How to Obtain SAMHSA Implementation Resource Kits.....	7
What To Include in Your Application.....	8
Face Page	
Abstract	
Table of Contents	
Budget Form	
Project Narrative and Supporting Documentation	
Appendices	
Assurances	
Certifications	
Disclosure of Lobbying Activities	
Checklist	
Returned Implementation Resource Kits	
Project Narrative – Sections A through D.....	10
Section A: Readiness	
Section B: Plans for Implementing the EBP(s)	
Section C: Training Plan	
Section D: Plan for Evaluating the Implementation of the EBP(s)	
SAMHSA’s Participant Protection.....	12
Special Considerations and Requirements .....	15
Appendix: Resources.....	15

## **Agency**

Department of Health and Human Services,  
Substance Abuse and Mental Health Services  
Administration

## **Purpose of This Announcement**

The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Mental Health Services (CMHS) is accepting applications for fiscal year 2003 (FY03) Best Practices funds for up to seven grants to engage and support States in implementing and evaluating evidence-based practices (EBPs). State applicants will select and implement one or more of the six EBPs for which SAMHSA has previously developed implementation Resource Kits. These grants will fund the States to (1) provide state-of-the-art training and continuing education to State mental health service providers and other stakeholders who are implementing the EBP(s), and (2) evaluate the implementation of selected EBPs in two or more communities within the State. Implementation of the EBP, aside from training/continuing education of providers, must be supported through other sources of funds.

It is expected that approximately \$2.2 million will be available for seven awards in FY03. The average annual award will range from \$250,000 to \$325,000 in total costs (direct and indirect). Cost-sharing is not required in this program. Actual funding levels will depend on the availability of funds. The amount of funds available will depend on SAMHSA's final FY03 budget appropriation.

Applications with proposed budgets that exceed \$325,000 will not be reviewed.

Awards may be requested for up to 3 years. Annual continuation awards will depend on the availability of funds and progress achieved.

## **Who Can Apply?**

Only State mental health authorities may apply. States are defined in Section 2 of the Public Health Service Act as including, in addition to the several States, only the

- District of Columbia
- Guam
- Commonwealth of Puerto Rico
- Northern Mariana Islands
- Virgin Islands
- American Samoa
- Trust Territory of the Pacific Islands (now Palau, Micronesia, and the Marshall Islands).

Only State mental health authorities are eligible, because they have primary responsibility for provision of public mental health services in the United States. As such, only the State mental health authorities generally can mandate the relationship between training and service provision that is necessary to make the implementation and evaluation of EBPs in multiple communities across the State a success.

## **Application Kit**

SAMHSA application kits include the following:

- 1. PHS 5161-1** - (*revised July 2000*) - Includes the face page, budget forms, assurances, certifications, and checklist.
- 2. PART I** - of the Request for Applications (RFA) includes instructions for the specific grant application. **This document is Part I.**

**3. PART II** - of the RFA provides general guidance and policies for SAMHSA grant applications. The policies in Part II that apply to this program are listed in this document under “Special Considerations and Requirements.” **You must use all of the above documents in completing your application.**

## **How To Get an Application Kit**

- Call the SAMHSA National Mental Health Information Center at (800) 789-CMHS, or
- Download **Part I, Part II, and the PHS 5161-1** of the application kit from the SAMHSA Web site at [www.samhsa.gov](http://www.samhsa.gov). Click on “Grant Opportunities” and then “Current Grant Funding Opportunities.”
- In addition to the application, **you may want to obtain draft copies of one or more of the implementation Resource Kits to be used for this grant program**. Please see the section, “How To Obtain SAMHSA Implementation Resource Kits.” If copies are requested, they must be returned with the application, or the application will not be reviewed.

## **Where To Send the Application**

Send the original and two copies of your grant application to:

**SAMHSA Programs**  
Center for Scientific Review  
National Institutes of Health  
Suite 1040  
6701 Rockledge Drive MSC-7710  
Bethesda, MD 20892-7710

**\*\*Change the zip code to 20817 if you use express mail or courier service.**

**All applications MUST be sent via a recognized commercial or governmental carrier. Hand-carried applications will not be accepted. Faxed or e-mailed applications will not be accepted. You will be notified by letter that your application has been received.**

If you require a phone number for delivery, you may use (301) 435-0715.

## **Application Due Date**

Your application must be received by March 24, 2003.

Applications received after this date must have a proof-of-mailing date from the carrier before March 17, 2003.

Private metered postmarks are not acceptable as proof of timely mailing. Late applications will be returned without review.

## **How To Get Help**

**For questions on program issues, contact:**

Crystal R. Blyler, Ph.D.  
Social Science Analyst  
SAMHSA Center for Mental Health Services  
5600 Fishers Lane, Room 11C-22  
Rockville, MD 20857  
(301) 594-3997 (direct)  
(301)443-3653 (central phone)  
E-mail: [cblyler@samhsa.gov](mailto:cblyler@samhsa.gov)

**For questions on grants management issues, contact:**

Stephan Hudak  
Division of Grants Management  
Substance Abuse and Mental Health Services  
Administration/OPS  
5600 Fishers Lane/ Rockwall II, 6<sup>th</sup> floor  
Rockville, MD 20857  
(301) 443-9666  
E-mail: shudak@samhsa.gov

## **Award Criteria**

Decisions to fund a grant are based on:

1. The strengths and weaknesses of the application as identified by the Peer Review Committee and approved by the CMHS National Advisory Council.
2. Availability of funds.
3. Geographic distribution; only one grant per State will be awarded, and CMHS will attempt to distribute the awards across various regions of the country.
4. SAMHSA Resource Kit selected; in order to gather evidence regarding the effectiveness of each of the six Resource Kits, CMHS will attempt to fund a combination of projects that together test all six Resource Kits.

Criteria 3 and 4 will be balanced against the other award criteria, particularly criterion number 1 regarding peer review.

**Note: Applications that do not include all copies of the implementation Resource Kits that the State received from SAMHSA for use in preparing the application WILL NOT BE REVIEWED.** See “How To Obtain SAMHSA Implementation Resource Kits.”

## **Post-Award Requirements**

1. Quarterly and annual progress reports.
2. Grantees must inform the Project Officer of any publications based on the grant project.
3. Grantees must provide information needed by SAMHSA to comply with the Government Performance and Results Act (GPRA) reporting requirements.

GPRA mandates accountability and performance-based management by Federal agencies, focusing on results or outcomes in evaluating the effectiveness of Federal activities and on measuring progress toward achieving national goals and objectives. Grantees must comply with GPRA data collection and reporting requirements.

For this program, GPRA results that awardees must report annually are:

- Number of communities in the State that are implementing EBP(s) using SAMHSA’s Resource Kits
  - Number of State providers trained in EBP implementation
  - Fidelity score for each State program implementing the EBP(s). Periodic assessment of program fidelity is a standard feature of the implementation of evidence-based practices. Examples of fidelity measurement tools are included in the SAMHSA Resource Kits. States will report fidelity data that they are collecting as part of their implementation efforts.
4. To ensure compliance with Code of Federal Regulations, Title 45, Part 46, revised November 13, 2001, regarding human subjects protection, the GPO will carefully review the evaluation plans outlined in the grant application. If it is

determined that Institutional Review Board approval is required, the grantee shall obtain such approval prior to implementing data collection.

## **Program Overview**

### *Background*

In recent years, the academic, policy, and provider communities, including SAMHSA, have paid increasing attention to the concept of EBP as it pertains to mental health service delivery. A consortium of researchers, public health administrators, private foundations, States, consumers, and family members have joined together to create the National Evidence-Based Practices Project (NEBPP) in order to develop the capacity for widespread use of EBPs within the public mental health system. SAMHSA has contributed to, supported, and expanded upon these efforts through a series of related activities:

1. The development of six EBP implementation *Resource Kits* covering the following practice areas:
  - supported employment
  - family psychoeducation
  - co-occurring disorders; integrated dual disorders treatment
  - assertive community treatment
  - medication management
  - illness management and recovery.
2. Funding a *National EBP Center*, operated by the National Association of State Mental Health Program Directors (NASMHPD) Research Institute, designed to stimulate the interest of States and their stakeholders in the use of the Resource Kits and the adoption of EBPs.
3. Commissioning the provision of evaluation technical assistance and cross-State analysis of results for the evaluation of the usefulness

and effectiveness of five of the Resource Kits (not including the medication management Resource Kit) being used to implement EBPs in an eight-State *National Demonstration* being conducted by the NEBPP. This evaluation will be completed in September 2005.

4. Cosponsoring a FY03 RFA (MH-03-007) with the National Institute of Mental Health (NIMH) to help States, through 1-year *planning grants*, plan activities bridging science and service.

The National EBP Center reports that all of the States have expressed interest in implementing and evaluating the implementation of EBPs. Although the joint NIMH-SAMHSA RFA provides money to States to *plan* such activities, it does not provide funding directly for EBP implementation or evaluation. In addition, although SAMHSA is supporting specific aspects of the National Demonstration, this support has not, thus far, included direct funding for the States. The EBP Training and Evaluation grants funded through this announcement will support States' evaluation of EBPs, as well as certain aspects of implementation (i.e., training and continuing education).

Although rigorous testing of the Resource Kits will not be completed until the National Demonstration ends in 2005, SAMHSA expects that the Resource Kits will be found to be effective tools for promoting change and helping States to implement EBPs. The evidence base for the practices themselves is solid, and the Resource Kits incorporate knowledge about the types of training that are necessary to effectively implement the practices, as well as the best ways to promote systems change. Therefore, SAMHSA wishes to take advantage of the States' current enthusiasm for EBPs by engaging and supporting them in our mutual goal of moving from science to service.

### *Program Goals and Objectives*

The EBP Training and Evaluation grant program will engage and support States in implementing and evaluating the implementation of EBPs by funding them to

1. provide state-of-the art training and continuing education to State mental health service providers and other stakeholders who are implementing EBP(s) using SAMHSA's Resource Kits, and
2. evaluate the implementation of each EBP in two or more communities within the State.

### *Program Structure*

Grantees will select for implementation one or more of the six EBPs for which SAMHSA has developed Resource Kits. The EBPs from which States may choose are supported employment, family psychoeducation, integrated treatment of co-occurring disorders, assertive community treatment, medication management, and illness management and recovery. Grantees will then use the Resource Kit(s) to implement the EBP(s) in a minimum of two communities within their States. Direct service delivery will be necessary during the grant period so that the effectiveness of the EBP implementation can be evaluated; however, ***grant money cannot be used to pay for direct service delivery***. Applicants must, therefore, demonstrate the State's commitment to and plan for implementing the EBPs in at least two communities to which the grant activities will be directed.

Grant money shall be used to provide training and continuing education to those involved in implementing the EBP(s). In keeping with SAMHSA's goal of engaging States in long-term promotion of EBPs, applicants must also describe how a mechanism will be established to provide EBP training and continuing education on an ongoing basis after the grant period has ended. For example, some States have suggested

plans to establish "Centers of Excellence" that would provide continued training and other dissemination services. Other States might wish to establish State training institutes or train-the-trainer networks, or build specific EBP training criteria into their credentialing systems. Although a variety of mechanisms are possible, the goal is to establish a sense of permanence regarding implementation of EBPs within the States.

Grant money shall also be used to conduct an evaluation of the EBP implementation. The implementation of the EBPs in accordance with guidelines provided in the Resource Kits themselves requires certain elements of ongoing evaluation to be incorporated into service provision. For example, the Resource Kits describe the need and methods for accomplishing ongoing assessments of program fidelity to the EBP model and key client outcomes. In addition, States may propose evaluations that examine a wide range of issues, such as

- strategies and barriers associated with implementation success
- contextual or organizational factors associated with success or failure to implement with fidelity
- assessments of the quality and effectiveness of the training program
- satisfaction of stakeholders with program implementation
- characteristics of program participants whom the program is or is not particularly successful at engaging, and/or for whom the program is/is not particularly successful
- sequential steps or organizational processes necessary to achieve implementation with fidelity
- any other quantitative or qualitative information that will contribute to the State's understanding of how to better promote the implementation of EBPs within the State.

In order to ensure that evaluations are of high quality and useful, ***at least 20% of the SAMHSA funds must be devoted to conducting the evaluation.*** To maximize program effectiveness, ***at least 50% of the SAMHSA funds must be devoted to training and continuing education.***

## **How To Obtain SAMHSA Implementation Resource Kits**

### **Pre-Application**

The SAMHSA-funded implementation Resource Kits are not yet available for distribution to the general public. We fully expect that the Resource Kits will be available for use when the grant awards are made. In the interim, in order to assist the States in preparing applications in response to this RFA, a limited number of copies of the written materials from the Resource Kits are available exclusively for perusal by potential applicants. ***Potential applicants must not reproduce these copies and must return them to SAMHSA with the grant application.*** SAMHSA will track which States have received copies of each Resource Kit. ***If the copies received by State applicants are not returned with the application, then the application WILL NOT BE REVIEWED.***

To receive draft copies of the Resource Kits for use in preparing the application, provide your name, position title, mailing address for receipt of packages, email address, and phone number to:

Crystal R. Blyler, Ph.D.  
Community Support Programs Branch  
SAMHSA Center for Mental Health Services  
(301)594-3997 (direct)  
(301)443-3653 (central phone)  
(301)443-0541 (fax)

cblyler@samhsa.gov

If States receiving copies of the Resource kits decide not to apply, then they must *return the copies* to Dr. Blyler at Room 11-C-22, 5600 Fishers Lane, Rockville, MD 20857, *no later than the application due date.*

### **Post-Award**

Within 15 business days following notification of grant awards, the Government Project Officer shall send each funded State 10 complete copies of the draft implementation Resource Kit(s) for the practice(s) that the State plans to implement and evaluate as part of this grant program. State needs for more or fewer copies can be negotiated with the Government Project Officer following grant award.

## **What To Include in Your Application**

In order for your application to be complete, it must include the following in the order listed. Check off areas as you complete them for your application.

### ☐ **1. FACE PAGE**

Use Standard Form 424, which is part of the PHS 5161-1 (revised July 2000). See Appendix A in Part II of the RFA for instructions. In signing the face page of the application, you are agreeing that the information is accurate and complete.

### ☐ **2. ABSTRACT**

Your total abstract should not be no longer than 35 lines. In the first five lines or less of your abstract, write a summary of your project that can be used, if your project is funded, in

publications, reporting to Congress, or press releases.

### ☐ **3. TABLE OF CONTENTS**

Include page numbers for each of the major sections of your application and for each appendix.

### ☐ **4. BUDGET FORM**

Standard Form (SF) 424A, which is part of the PHS 5161-1 (revised July 2000) is to be used for the budget. Fill out Sections B, C, and E of the SF 424A. Follow instructions in Appendix B of Part II of the RFA.

### ☐ **5. PROJECT NARRATIVE AND SUPPORTING DOCUMENTATION**

**The Project Narrative describes your project. It consists of Sections A through D.** These sections may be no longer than 20 pages. More detailed information about Sections A through D follows #10 of this checklist.

- ☐ **Section A** – Readiness
- ☐ **Section B** – Plans for Implementing the EBP(s)
- ☐ **Section C** – Training Plan
- ☐ **Section D** – Plan for Evaluating the Implementation of the EBP(s)

**The Supporting Documentation section of your application provides additional information necessary for the review of your application. This supporting documentation should be provided immediately following your Project Narrative in Sections E through H.** There are no page limits for these sections, except for Section G, the Biographical Sketches/Job Descriptions.

- ☐ **Section E** – Literature Citations. This section must contain complete citations, including titles, dates, and all authors, for any literature you cite in your application.
- ☐ **Section F** – Budget Justification, Existing Resources, Other Support. You must provide a narrative justification of the items included in your proposed budget as well as a description of existing resources and other support you expect to receive for the proposed project. **(See Part II of the RFA, Example A, Justification).**
- ☐ **Section G** – Biographical Sketches and Job Descriptions
  - Include a biographical sketch for the project director and for other key positions. Each sketch should be no longer than **two pages**. If the person has not been hired, include a letter of commitment from the individual with a current biographical sketch.
  - Include job descriptions for key personnel. They should be no longer than **one page**.
  - **Sample sketches and job descriptions are listed on page 22, Item 6 in the Program Narrative section of the PHS 5161-1.**
- ☐ **Section H** – SAMHSA's Participant Protection. The elements you need to address in this section are outlined after the Project Narrative description in this document.

### ☐ **6. APPENDICES 1 THROUGH 4**

- Use only the appendices listed below.
- **Do not** use appendices to extend or replace any of the sections of the Project Narrative unless specifically required in this RFA (reviewers will not consider them if you do).

**Appendix 1:** Data Collection  
Instruments/Interview Protocols

**Appendix 2:** Sample Consent Forms

**Appendix 3:** Letters of Coordination/Support

**Appendix 4:** Non-Supplantation of Funds

☐ **7. ASSURANCES**

Non-Construction Programs. Use Standard Form 424B found in PHS 5161-1 (revised July 2000).

☐ **8. CERTIFICATIONS**

Use the "Certifications" forms, which can be found in PHS 5161-1. See Part II of the RFA for instructions.

☐ **9. DISCLOSURE OF LOBBYING ACTIVITIES** (See form in PHS 5161-1)

Appropriated funds, other than for normal and recognized executive-legislative relationships, may not be used for lobbying the Congress or State legislatures. Federal law prohibits the use of appropriated funds for publicity or propaganda purposes or for the preparation, distribution, or use of information designed to support or defeat legislation pending before the Congress or State legislatures. This includes "grass roots" lobbying, which consists of appeals to members of the public suggesting that they contact their elected representatives to indicate their support for or opposition to pending legislation, or to urge those representatives to vote in a particular way. (Please read **Part II** of the RFA, General Policies and Procedures for all SAMHSA Applications, for additional details.)

☐ **10. CHECKLIST** (Found in PHS 5161)

You must complete the checklist. See Part II, Appendix C, of the RFA for detailed instructions.

☐ **11. RETURNED IMPLEMENTATION RESOURCE KITS**

Any copies of the implementation Resource Kits that the State received from SAMHSA for use in preparing the application must be returned with the application. *If the copies are not returned with the application, then the application will not be reviewed.*

## **Project Narrative**

### **Sections A through D**

In developing your application, use the instructions below that have been tailored to this program. These are to be used in lieu of the "Program Narrative" instructions found in the PHS 5161-1 on page 21.

**Sections A through D are the Project Narrative of your application.** These sections describe what you intend to do with your project. Below you will find detailed information on how to respond to Sections A through D. Sections A through D may be no longer than 20 pages.

- **Your application will be reviewed and scored against the requirements described below for Sections A through D. These sections also function as review criteria.**
- A peer review committee will assign a point value to your application based on how well you address **each** of these sections.
- The number of points after each main heading shows the maximum number of points a review committee may assign to that category.
- Bullet statements do not have points assigned to them; they are provided to invite attention to important areas within the criterion.

- Reviewers will also be looking for evidence of cultural competence **in each section** of the Project Narrative. Points will be assigned based on how well you address cultural competency aspects of the review criteria. SAMHSA's guidelines for cultural competence are included in Part II of the RFA, Appendix D.

### **Section A: Readiness 10 points**

<Describe the importance and relevance of the evidence-based practices movement to the improvement of mental health service delivery in your State.

<Describe how this grant funding will contribute to your State's efforts to implement EBPs.

<Identify the EBP(s) you have selected to implement under this RFA and describe your rationale for the selection.

<Justify the need for the selected EBP(s) in your State.

<Describe any previous work done in the State to set the stage for the implementation and evaluation of the selected EBP(s).

<Describe how the decision to implement and evaluate the particular EBP(s) selected was made, including how input from diverse stakeholder groups was solicited and incorporated into the decisionmaking process.

### **Section B: Plans for Implementing the EBP(s) 20 points**

<Identify at least two communities in which the EBP(s) will be implemented and evaluated under this RFA. Describe the population demographics of the selected communities, such as age, gender, race, ethnicity, and languages

spoken. In Appendix 3, include letters of coordination/support from the Executive Directors of the local organizations that will implement the EBP(s) in the selected communities.

<Provide a detailed description of your organizational and management plans for implementing the EBP(s) in these communities using the SAMHSA Resource Kit(s). Use charts as necessary to present the information clearly and succinctly.

<Describe your plans for establishing a system for assessing program fidelity and client outcomes on an ongoing basis as part of the implementation.

<Describe staff roles and responsibilities regarding the EBP implementation, as well as staff qualifications for key positions. [Include biographical sketches for key staff in Section G of your application.]

<Describe how the implementation and services to be provided will be funded.

<Describe how the programs to be implemented will take the diversity of the communities into account in providing services.

<Describe the roles of diverse stakeholder groups in implementing the EBP(s).

<Provide a table of implementation activities and interim goals and the time periods in which they will be completed.

### **Section C: Training Plan 35 points**

<Provide a detailed description of your organizational and management plans for providing training and continuing education regarding the selected EBP(s) to providers and other stakeholders throughout the grant period.

<Identify the staff members who will be responsible for various aspects of training and continuing education. Describe the qualifications of these staff members to provide such training. (Include biographical sketches in Section G of your application.)

<Specifically describe how training regarding consumer and family member sensitivity and cultural competence will be provided.

<Specifically describe how training regarding the use of ongoing evaluation of program fidelity and client outcomes for continuous quality improvement will be provided.

<Provide a table of training and continuing education activities and goals and the time periods in which they will be completed.

<Describe the system through which you will keep track of the number of State providers trained in implementing the EBP(s).

<Describe how a mechanism will be established to provide EBP training and continuing education on an ongoing basis after the grant period has ended.

**Section D: Plan for Evaluating the Implementation of the EBP(s)**  
**35 points**

<Fully describe how you will evaluate the success of the EBP training and continuing education efforts, as well as the EBP implementation itself.

<Fully describe the evaluation protocol you intend to use. Include evaluation instruments to be used in Appendix 1. Describe any literature or pilot testing done to verify the validity and reliability of the instruments to be used.

<Describe how you will manage and coordinate the evaluation within and across sites within the State.

<Describe how the data to be collected will contribute to the State's understanding of how to better promote the implementation of EBP(s).

<Describe how the data collected will be analyzed. Include any analyses that will be done to determine the effectiveness of the implementation for diverse subgroups, as well as the satisfaction of various stakeholder groups with the implementation process and result.

<Identify the staff members who will conduct the evaluation, and describe their qualifications regarding the evaluation of mental health service implementation.

<Describe how the formal evaluation will relate to the ongoing program fidelity assessment and client outcome measurement systems that will be established as part of EBP implementation.

<Provide a table of evaluation activities and goals and the time periods in which they will be completed. Clearly indicate the interconnection between the evaluation and implementation timelines.

**NOTE:** Although the budget for the proposed project is not a review criterion, the Review Group will be asked to comment on the appropriateness of the budget after the merits of the application have been considered.

## **SAMHSA'S Participant Protection**

Part II of the RFA provides a description of SAMHSA's Participant Protection Requirements

and the Protection of Human Subjects Regulations.

For this RFA, applicants must follow the SAMHSA Participant Protection Requirements in preparing their applications. Review of the applications by the Peer Review group and SAMHSA staff may indicate that some proposals will require additional Human Subjects Protections, such as review by an Institutional Review Board.

SAMHSA will place restrictions on the use of funds until all participant protection issues are resolved. Problems with participant protection identified during peer review of your application may result in delay of funding. See Part II of the RFA for more information on participant protection.

You must address each element regarding participant protection in your supporting documentation. If any one or all of the elements is not relevant to your project, you must document the reasons that the element(s) does not apply.

This information will:

1. Reveal if the protection of participants is adequate or if more protection is needed.
2. Be considered when making funding decisions.

Projects may expose people to risks in many different ways. In this section of your application, you will need to:

- Identify and report any possible risks for participants in your project.
- State how you plan to protect participants from those risks.

- Discuss how each type of risk will be dealt with, or why it does not apply to the project.

Each of the following elements must be discussed:

→ Protect Clients and Staff From Potential Risks

- Identify and describe any foreseeable physical, medical, psychological, social, legal, or other risks or adverse effects.
- Discuss risks that are due either to participation in the project itself, or to the evaluation activities.
- Describe the procedures that will be followed to minimize or protect participants against potential risks, including risks to confidentiality.
- Give plans to provide help if there are adverse effects to participants.
- Where appropriate, describe alternative treatments and procedures that may be beneficial to the participants. If you do not decide to use these other beneficial treatments, provide the reasons for not using them.

^ Fair Selection of Participants

- Describe the target population(s) for the proposed project. Include age, gender, and racial/ethnic background, and note if the population includes homeless youth, foster children, children of substance abusers, pregnant women, or other specific groups.
- Explain the reasons for including groups of pregnant women, children, people with mental disabilities, people in institutions, prisoners, or others who are likely to be vulnerable to HIV/AIDS.

- Explain the reasons for including or excluding participants.
- Explain how you will recruit and select participants. Identify who will select participants.

#### ✓ Absence of Coercion

- Explain if participation in the project is voluntary or required. Identify possible reasons why it may be required: for example, court orders requiring people to participate in a program.
- If you plan to pay participants, state how they will be given money or gifts.
- State how volunteer participants will be told that they may receive services and incentives even if they do not complete the study.

#### ⇔ Data Collection

- Identify from whom you will collect data: participants themselves, family members, teachers, or others. Describe the data collection procedure and specify the sources for obtaining data: school records, interviews, psychological assessments, questionnaires, observation, or other sources. Where data are to be collected through observational techniques, questionnaires, interviews, or other direct means, describe the data collection setting.
- Identify what type of specimens (e.g., urine, blood) will be used, if any. State if the material will be used just for evaluation or if other use(s) will be made. Also, if needed, describe how the material will be monitored to ensure the safety of participants.
- Provide in Appendix 1, “Data Collection Instruments/Interview Protocols,” copies of

all available data collection instruments and interview protocols that you plan to use.

#### ⇐ Privacy and Confidentiality

- Explain how you will ensure privacy and confidentiality. Include who will collect data and how it will be collected.
- Describe:
  - < How you will use data collection instruments.
  - < Where data will be stored.
  - < Who will or will not have access to information.
  - < How the identity of participants will be kept private, such as through the use of a coding system on data records, limiting access to records, or storing identifiers separately from data.

**NOTE:** If applicable, grantees must agree to maintain the confidentiality of alcohol and drug abuse client records according to the provisions of Title 42 of the Code of Federal Regulations, Part II.

#### ↑ Adequate Consent Procedures

- List what information will be given to people who participate in the project. Include the type and purpose of their participation. Include how the data will be used and how you will keep the data private.
- State:
  - < If their participation is voluntary.
  - < Their right to leave the project at any time without problems.
  - < Possible risks from the project.
  - < Plans to protect clients from these risks.
- Explain how you will get consent for youth, the elderly, people with limited reading skills, and people who do not use English as their first language.

NOTE: If the project poses potential physical, medical, psychological, legal, social, or other risks, participants **must** give written informed consent.

- Indicate if you will get informed consent from participants or from their parents or legal guardians. Describe how the consent will be documented. For example: Will you read the consent forms? Will you ask prospective participants questions to be sure they understand the forms? Will you give them copies of what they sign?
- Include sample consent forms in Appendix 2, titled “Sample Consent Forms.” If needed, give English translations.

**NOTE:** Never imply that the participant waives or appears to waive any legal rights, may not end involvement with the project, or releases your project or its agents from liability for negligence.

- Describe if separate consents will be obtained for different stages or parts of the project. For example, will they be needed for both participant protection in treatment intervention and for the collection and use of data?
- Additionally, if other consents (e.g., consents to release information to others or gather information from others) will be used in your project, provide a description of the consents. Will individuals who do not consent to having individually identifiable data collected for evaluation purposes be allowed to participate in the project?

#### ⇒ Risk/Benefit Discussion

Discuss why the risks are reasonable compared with expected benefits and importance of the knowledge from the project.

## **Special Considerations and Requirements**

SAMHSA’s general policies and special considerations/requirements related to this program are found in **Part II** of the RFA. The following sections are applicable to this RFA:

- Population Inclusion Requirement
- Government Performance Monitoring
- Consumer Bill of Rights and Responsibilities
- Promoting Nonuse of Tobacco
- Supplantation of Existing Funds
- Letter of Intent (optional—must be submitted by February 21, 2002)
- Coordination With Other Federal/Non-Federal Programs
- Intergovernmental Review (E.O. 12372)
- Confidentiality/SAMHSA Participant and Human Subject Protection

## **Appendix: Resources**

In addition to the SAMHSA personnel listed under “How To Get Help,” the following resources may be useful to you in completing your application and project.

For information about the SAMHSA-funded Resource Kits and the National Demonstration and its evaluation, see the project Web site at <http://mentalhealthpractices.org>.

For assistance in determining which EBP to implement, information about the National Demonstration and its evaluation, and issues regarding implementation of EBPs, call the SAMHSA-funded National EBP Center at (703) 739-9333.

For assistance regarding planning or conducting an evaluation of EBP implementation, contact the SAMHSA-funded Technical Assistance Center for the Evaluation of Mental Health Systems Change at (617) 876-0426, or see their Web site at [www.tecathsri.org](http://www.tecathsri.org).

For more information about the NIMH-SAMHSA joint RFA on State Implementation of Evidence-based Practices: Bridging Science and Service, see the announcement at <http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-03-007.html>. The deadline for applications for these planning grants was October 29, 2002.